Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13414

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION (HFD-730)
ROCKVILLE, MD 20857

ADVERSE REACTION REPORT
(Drugs and Biologics)

Form Approved: OMB No. 0910-0230. 1304

FDA CONTROL NO. 13414

ACCESSION NO.

I. REACTION INFORMATION

1. PATIENT ID/INITIALS (In Confidence) [redacted]

2. AGE YRS. 19

3. SEX F

4.-6. REACTION ONSET MO. DA. YR.

7. DESCRIBE REACTION(S)
heart pounding then chest pain then shaking. Dizzy

13. RELEVANT TESTS/LABORATORY DATA
EKG & Sig Δ. - T wave inversion III only

8.-12. CHECK ALL APPROPRIATE:
- ☐ PATIENT DIED
- ☐ REACTION TREATED WITH Rx DRUG
- ☐ RESULTED IN, OR PROLONGED, INPATIENT HOSPITALIZATION
- ☐ RESULTED IN PERMANENT DISABILITY
- ☒ NONE OF THE ABOVE

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (Give manufacturer and lot no. for vaccines/biologics)
MetABOLIFE

15. DAILY DOSE

16 ROUTE OF ADMINISTRATION
ORAL

17. INDICATION(S) FOR USE "wt loss"

18. DATES OF ADMINISTRATION (From/To)
2/16/99 - 3/1/99

19 DURATION OF ADMINISTRATION
2 wks

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☒ NO ☐ NA

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ YES ☐ NO ☒ NA

III. CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat reaction)
Depo Provera alt & Lupron

23. OTHER RELEVANT HISTORY (e.g. diagnoses, allergies, pregnancy with LMP, etc.)
Also consuming caffeine beverages

MAR 1999
RECEIVED
DOMESTIC PROGRAMS BRANCH
CONSUMER COMPLAINT COORD.

IV. REPORTS SUBMITTED BY MANUFACTURER

24. NAME AND ADDRESS OF MANUFACTURER (Include Zip Code)
REC'D
MAR 16 1999
MEDWATCH CTU

24a. IND/NDA. NO. FOR SUSPECT DRUG

24b MFR. CONTROL NO.

24c. DATE RECEIVED BY MANUFACTURER

24d. REPORT SOURCE (Check all that apply)
☐ FOREIGN ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ CONSUMER

25 15 DAY REPORT?
☐ YES ☐ NO

25a. REPORT TYPE
☐ INITIAL ☐ FOLLOWUP

CFU 99382

V. INITIAL REPORTER (In confidence)

26.-26a. NAME AND ADDRESS OF REPORTER (Include Zip Code)
[redacted]

26b. TELEPHONE NO. (Include area code)

26c. HAVE YOU ALSO REPORTED THIS REACTION TO THE MANUFACTURER?
☐ YES ☒ NO

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26d. ARE YOU A HEALTH PROFESSIONAL?
☒ YES ☐ NO

NOTE: Required of manufacturers by 21 CFR 314.80

Submission of a report does not necessarily constitute an admission that the drug caused the adverse reaction.

Adverse Event Questionnaire

Complaint Number: 13414 **Investigator: Gary Coody**

Consumer Information

Date of Report: 06/10/1999

Initial Report Source: ☐ORA Consumer Injury
☐Telephone ☐Correspondence ☒MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted]

Gender: ☒F ☐M

Age:19

Race: ☐1-White ☐2-Black ☐3-Asian/Pacific Islander ☒4-Native American ☐5-Hispanic
☐8-Other ☐9-Unknown

Information on Adverse Event

Date of Adverse Event: 03/02/1999
Previous Adverse Effects to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office):
Home

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):
After taking Metabolife for 2 weeks, experienced chest pains, heart pounding, dizziness, sweaty, jittery, and felt faint the morning of 03/02/1999. Co-worker took her to MD office at around 11:00am. She rested in the office, MD performed EKG, and she left around 2pm. She "got rid" of product so no consumer sample is available.

How long did the symptoms last?
Three or four days.

Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.).
Started taking Metabolife approximately 2 weeks before the event. Normally took one in the morning with food, one with lunch, and one at 4pm. She did not take on morning of the adverse event because she skipped breakfast. Last dose was 2pm the previous day.

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
Minocin, contraceptives

Did event abate after use of suspected product stopped or dose reduced: ☒Yes ☐No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number:
[redacted]

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☐Other (specify)

What medical tests were performed and what were the results?
EKG,
What was the medical diagnosis? Possible withdrawal from stimulant of Metabolife
What treatment(s) was given (e.g., drugs, other)? No

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Were there any preexisting condition(s)/treatment(s)? Morbidly obese, ovarian cyst (patient will have surgery on ovaries on 06/17/1999.
(If YES, list them including allergies, and chronic diseases): ☒Yes ☐No Allergic to Demerol

Product Category

1. Adverse event attributed to:
   ☐**Medical Food** (under medical supervision) ☐**Infant Formula**
   ☐**Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   ☐**Other** (traditional food) _____

Other Product Problems

2. ☐Foreign Object (specify):_____

3. ☐Other (specify): _____

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

Patient discarded consumer sample.

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☐Check here if ingredients are unknown

_____

_____

_____

_____

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

☐Aspartame
☐Monosodium Glutamate
☐Sulfite
☐Other_____
☐Unknown

☐Color Additive (please specify) _____

Is the product label available, if yes submit a quality copy along with this questionnaire: ☐Yes ☐No ☐Unknown Product Sample Available: ☐Yes ☐No ☐Unknown

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records)

Death: ☐Yes ☐No

Life-Threatening: ☐Yes ☐No

Hospitalization: ☐Yes ☐No (if YES, indicate if initial or prolonged) _____

Required intervention to prevent permanent impairment/damage: ☐Yes ☐No

Did the adverse event result in a congenital anomaly: ☐Yes ☐No